

Application No. 10/802,908
Amendment dated April 30, 2007
Reply to Office Action of October 31, 2006

REMARKS

Applicant amended independent claim 7 and dependent claims 29-31 to further define Applicant's claimed invention.

I. 35 U.S.C. § 112 Rejection

In the Office Action, the Examiner rejected claim 31 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant amended claims 29, 30, and 31 to provide proper antecedent basis. Applicant submits that the rejection of claim 31 under 35 U.S.C. § 112, second paragraph has been overcome.

II. 35 U.S.C. § 102 and 103 Rejections

The Examiner rejected claims 7-10, 13-16, 18-29, 31, 35, and 37-41 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 2,825,329 to Caesar ("Caesar"); and rejected claims 30, 32-34 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Caesar. Applicant respectfully traverses the Examiner's rejections.

Independent claim 7 recites an implant having a bone contacting surface, "a substantial portion of said bone contacting surface being one of convex along the length of said body and flat along the length and width of said body." Fig. 3 of Caesar shows that the bone-contacting surface of plate 150 is concave along the width of the plate to conform to the shape of the bone on which the plate sits. Caesar does not teach or suggest a plate with a substantial portion of the bone contacting surface being one of convex along the length of said body and flat along the length and width of said body as recited in independent claim 7.

Independent claim 7 recites a locking element "adapted to be coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." Applicant respectfully disagrees with the Examiner's assertion that plate 140 is "a locking element capable of locking the screws." (Office Action, page 3, line 3). Caesar teaches that "when the pins 152 are entered in the openings 70a and the plate 150 pressed into place, these pins 152 pass through the openings 144 in the plate 140," and "the ends of pins 152...just project from the opposite side of the bone." (Caesar,

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col. 3, lines 2-6) (emphasis added). Caesar further teaches that the turned down ends 160 of screws 158 enter the threaded openings 146 of the plate 140, and that as each screw advances, the screw threads will enter the threads in opening 146 of plate 140. (Caesar, col. 3, lines 11-17). Plate 140 of Caesar is coupled to the implant as a result of the insertion of the bone screws 158 into the bone screw receiving holes 146. Caesar does not teach or suggest a locking element adapted to be coupled to the implant prior to the insertion of the bone screws as recited in independent claim 7.

Further, Applicant respectfully disagrees with the Examiner's assertion that plate 140 can "merely cover the top of plate (150) and be rotated, slid, etc into and out of alignment for allowing the screws through holes (156)." (Office Action, page 3, lines 3-5). In Caesar, plate 140 is slid into a slot 94a formed in the bone portion itself. (Caesar, col. 2, lines 45-50). Caesar does not teach positioning plate 140 over the top of plate 150. Applicant respectfully submits that the modification proposed by the Examiner is a result of improper hindsight obtained from Applicant's disclosure. Applicant also submits that if plate 140 of Caesar covered the top of plate 150, then: (1) the flat shape of plate 150 would not correspond to the curved shape of plate 140 and potentially impinge on the surrounding tissue; and (2) plate 150 would not secure plate 140 to the bone, rendering the Caesar plate unworkable for its intended purpose.

Independent claim 7 recites a locking element "movable from an initial position that permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that is adapted to retain at least two bone screws to said implant." Caesar teaches that after the threads of screws 158 enter the threads in openings 146 of plate 140, "the screw can be driven home without any relative motion taking place between the plates 150 and 140." (Caesar, col.3, lines 16-19). Caesar also discloses that after the insertion of the screws, the screws "prevent shifting of the plate 140." (Caesar, col. 3, lines 44-46). In Caesar, plate 140 remains in the same position prior to and after the insertion of the screws 158. Caesar does not teach a locking element movable from an initial position that permits the insertion of at least one bone screw to a final position that is adapted to retain at least two bone screws to the Implant as recited in independent claim 7.

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Applicant submits that independent claim 7 is novel over Caesar, and that claims 8-10, 13-16, 18-29, 31, 35, and 37-41, dependent from independent claim 7, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Applicant submits that the rejection of claims 30, 32-34, and 36 is rendered moot at least because these claims depend from an allowable independent claim or claims dependent therefrom.

III. Double Patenting Rejections

The Examiner rejected claims 7-41 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-185 of U.S. Patent No. 7,118,573; claims 1-160 of U.S. Patent No. 7,044,952; claims 1-227 of U.S. Patent No. 7,041,105; claims 1-220 of U.S. Patent No. 6,527,776; claims 1-173 of U.S. Patent No. 6,193,721; claims 1-39 of U.S. Patent No. 6,936,051; and claims 1-117 of U.S. Patent No. 6,398,783; in view of U.S. Patent No. 5,468,242 to Reisberg ("Reisberg"). Applicant is submitting concurrently herewith a Terminal Disclaimer to overcome the Examiner's obviousness-type double patenting rejections over U.S. Patent Nos. 7,118,573; 7,044,952; 7,041,105; and 6,527,776.

Applicant hereby acknowledges the Examiner's provisional obviousness-type double patenting rejections over co-pending Application Nos. 10/926,734, and 11/128,556. Applicant reserves the right to revisit these rejections upon allowance of these applications to determine if a Terminal Disclaimer is required at that time.

Applicant respectfully traverses the Examiner's double patenting rejections as to U.S. Patent Nos. 6,936,051 ("051 patent"), 6,193,721 ("721 patent"), and 6,398,783 ("783 patent") for at least the reasons set forth below.

A. The Combination of the '051, '721 and '783 Patents With Reisberg Does Not Make Applicant's Claimed Invention Obvious

The MPEP states that the "analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination." (See MPEP § 804(II)(B)(1), page 800-21, Rev. 5, Aug. 2006). According to the MPEP, "[t]o establish a *prima facie* case of obviousness, three

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basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (See MPEP § 706.02(j), page 700-48, Rev. 5, Aug. 2006). Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness with respect to Applicant's claimed invention.

1. No Suggestion or Motivation to Combine the References

The MPEP teaches that "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so." (See MPEP, 2143.01 (I), page 2100-127, Rev. 5, Aug. 2006). The '051, '721, and '783 patents each teach an anterior cervical plate shaped with a bottom bone-contacting surface that is concave along the longitudinal axis of the plate. The "concave curvature [of the plate] in the longitudinal plane conforms to the proper shape of the anterior aspect of the spine with the vertebrae aligned in appropriate lordosis." ('051 patent, col. 13, lines 17-25; '721 patent, col. 13, lines 30-38; '738 patent, col. 13, lines 15-23) (emphasis added).

Applicant submits that there is no suggestion or motivation in the '051, '721, or '738 patents to modify the plate such that the bone-contacting surface of the plate is convex or flat as recited in Applicant's independent claim 7. Reisberg does not teach anterior cervical plates. Instead, Reisberg teaches a mesh plate that could be "contoured to a concave or convex anatomical shape by the surgeon at the time of the operation." (Reisberg, col. 1, lines 34-36). Modifying the concave bone-contacting surface of the plate claimed in the '051, '721, and '738 patents to be convex would prevent the plate from conforming to the shape of the anterior aspect of the cervical spine. One of ordinary skill would not be motivated to combine Reisberg's teachings with the claimed inventions of the '051, '721, and '783 patents.

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2. No Reasonable Expectation of Success in the Combination

Applicant further submits that one of ordinary skill would not have a reasonable expectation of success when combining the teachings of Reisberg to modify the claimed inventions of the '051, '721, and '738 patents. The plates taught in the '051, '721, and '738 patents have a concave bone-contacting surface along the longitudinal axis of the plate to conform to the natural shape of the anterior aspect of the cervical spine. Assuming, *arguendo*, that these concave plates were capable of being contoured so as to form a convex bone-contacting surface as taught in Reisberg, one of ordinary skill in the art could not have a reasonable expectation of success applying a plate with a convex bone-contacting surface to the convex-shaped anterior cervical spine. Such a convex plate would not work for the purpose intended in the '051, '721, and '738 patents.

3. The Proposed Combination Does Not Teach All Elements of Applicant's Claimed Invention

Applicant further submits that the combination of the '051, '721, and '738 patents with Reisberg fails to teach all of the limitations of Applicant's independent claim 7. If the plates of the '051, '721, and '738 patents were modified in view of Reisberg such that their bone-contacting surfaces were convex, the '051, '721, and '738 patents would still fail to teach or suggest "an orthopedic implant for engaging at least one non-vertebral bone of the human body" as recited in independent claim 7.

Applicant submits that the Examiner failed to establish a *prima facie* case of obviousness with respect to Applicant's claimed invention. Thus, the double patenting rejection over the '051, '721, and '783 patents in view of Reisberg is improper.

B. The '051, '721, and '783 Patents Are Not Properly Combinable With Reisberg

Applicant respectfully submits that combining Reisberg with any one of the '051, '721, or '783 patents is improper because such a combination would make the '051, '721, and '783 patents unworkable for their intended purpose.

The '051 and '783 patents each claim a plate system and plate, respectively, for use in "the anterior human cervical spine," and "the lower surface of the plate being

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concave along a substantial portion of the longitudinal axis" of the plate. (See, e.g., '051 patent, claim 1; '783 patent, claim 1). The '721 patent recites an "anterior cervical plate for engaging at least two vertebral bodies of a human cervical spine." (See, e.g., claim 1). Conversely, Applicant's independent claim 7 recites an orthopedic implant "for engaging at least one non-vertebral bone of the human body," a substantial portion of the bone contacting surface of which is "one of convex along the length of said body and flat along the length and width of said body." (Emphasis added).

Applicant respectfully disagrees with the Examiner's assertion that in view of Reisberg, "applicant's numerous patents attempting to differentiate bone plates on the premise of concave vs. convex/flat are not novel." (Office Action, page 7, lines 8-9). If the concave plates of the '051, '721, and '783 patents were contoured to have a convex or flat bone contacting surface, the shape of the plates would no longer correspond to the natural anatomical curvature of the cervical vertebral bodies and the plates would fail to work for their intended purpose. Thus, Applicant submits that modifying the implants of the '051, '721, and '783 patents by changing the lower surface of the implants from concave to flat or convex would make such implants unworkable for their intended purpose.

C. The Claims of the '051, '721, and '783 Patents are Patentably Distinct From Applicant's Claimed Invention

According to the MPEP, "[t]he general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not the second, while a second claim recites limitations disclosed only for the second species but not the first." (MPEP § 806.04 (b)). Independent claim 7 recites "an orthopedic implant for engaging at least one non-vertebral bone of the human body" and a substantial portion of bone-contacting surface being one of "convex along the length of said body and flat along the length and width of said body." These recitations of claim 7 exclude the recitations of claims in the '051, '721, and '783 patents, which are directed to inventions for application in the "anterior cervical spine." Modifying the plates claimed in the '051,

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'721, and '783 patents to have a convex or flat bone-contacting surface would make these plates unworkable for their intended purpose.

The bone-contacting surface being one of flat and convex as recited in claim 7 of the present application is a feature that is exclusive to areas outside of the anterior cervical spine due to the convex curvature of the anterior cervical spine. Conversely, all of the independent claims in the '051, '721, and '783 patents are directed to inventions for application in the "anterior human cervical spine."

Independent Claim 1 of the '051 patent recites a lock having an elongated segment having a width, a length longer than said width, the "lock being adapted to retain at least two bone screws to said plate when said length of said elongated segment is generally transverse to the longitudinal axis of said plate." Independent claim 1 of the '721 patent recites "a recess associated with said at least first and second of said bone screw receiving holes, said recess having a configuration for retaining a locking element," the "central longitudinal axis of said recess being offset from a transverse line passing through the central longitudinal axis of said first and second bone screw receiving holes." Applicant's independent claim 7 does not recite the above-identified recitations.

Applicant submits that independent claim 7 is directed to a patentably different invention as compared with the claimed inventions recited in the '051, '721, and '783 patents.

D. The Claims of the '051, '721, and '783 Patents are Not a Species of Applicant's "Generic" Claim 7

Applicant respectfully disagrees with the Examiner's assertion that the claimed inventions in the '051, '721, and '783 patents "define a 'species' of the 'generic' invention of claim 7." (Office Action, page 7, lines 14-15). As set forth above, Applicant's independent claim 7 is directed to "an orthopedic implant for engaging at least one non-vertebral bone of the human body" and having a bone-contacting surface "adapted to be placed against the at least one non-vertebral bone." All the independent claims in the '051, '721, and '783 patents recite application of plates to the "anterior

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cervical spine." Applicant submits that the claims of the present application are directed to a different field of surgery and represent a distinct species as compared with the claims of the '051, '721, and '783 patents. Applicant submits that claims of the present application are not generic to the claims of the '051, '721, and '783 patents, and are therefore not "anticipated" by the "species" of the '051, '721, and '783 patents.

Applicant submits that the double patenting rejections have been overcome.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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